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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,191	11/25/2003	Madalene C.Y. Heng		9054

7590 05/18/2006

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EXAMINER

AHMED, HASAN SYED

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/723,191	HENG, MADALENE C.Y.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Hasan S. Ahmed	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                       |                                                                                        |
|-----------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____                                                |

### **DETAILED ACTION**

Receipt is acknowledged of the application filed on 25 November 2003.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Specifically, claims 1 and 7 recite "...an enzyme which digests a cementing substance contained within the epidermis skin." However, the specification does not disclose which particular enzyme is being referred to and which particular cementing substance is the target of the recited enzyme. Nor does it disclose a mechanism of action by which said enzyme digests said cementing substance.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Specifically, claims 1 and 7 recite a generic "enzyme" and a generic "cementing substance" without disclosing a particular enzyme or cementing substance.

Furthermore, claim 7 recites "[a] medicine for treating acne..." suggesting a singular formulation. However, the claim goes on to recite a treatment regimen comprising an orally administered agent, as well as a topical composition. It is unclear which formulation, if any, the preamble refers to. Claims 8-11 are rejected because they depend from claim 7.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Beerse, et. al. (U.S. Patent No. 6,294,186).

Beerse, et. al. disclose a composition for the treatment of acne (see col. 3, lines 49-63).

The disclosed composition is the instant composition as claimed. A disclosed anti-inflammatory agent is, *inter alia*, the curcumin of instant claim 2 (see col. 22, line 35). A disclosed "second agent" is, *inter alia*, the ascorbic acid and citric acid of claim 3 (see col. 20, line 17; col. 56, line 21).

The stimulation of production of an enzyme which digests a cementing agent contained within the epidermis recited in claim 1 is deemed an inherent physiological response to the disclosed active agents.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beerse, et. al. (U.S. Patent No. 6,294,186) in view of Mezick (U.S. Patent No. 4,487,782).

Beerse, et. al. teach a composition for the treatment of acne (see above).

The disclosed composition is comprised of 0-98% water (see col. 9, line 31); 0-95% alcohol (see col. 9, lines 40-43); 0.01-10% cellulose (see col. 9, line 61; col. 10, line 40); 0.1-10% urea (see col. 36, lines 20-22); 0.3% carbomer (see examples 11-15); and .001-10% curcumin (see col. 20, line 41; col. 22, line 36).

The disclosed composition exhibits a pH in the range of about 1 to about 7 (see col. 19, lines 37-42).

The Beerse, et. al. reference differs from the instant case only in that it does not disclose use of high doses of orally administered Vitamin A in conjunction with topical application of an acne treatment.

Mezick teaches a method for treating acne (see col. 1, lines 6-7). Mezick explains that large oral doses of vitamin A, at doses of 300,000 – 500,000 I.U., are known to be beneficial in the treatment of acne (see col. 1, lines 50-59).

A person of ordinary skill at the time of the invention would therefore find motivation to combine oral doses of vitamin A with a topical treatment for acne as taught by Beerse, et. al. in view of Mezick. Motivation to combine these therapeutic approaches would come from increased efficacy in the treatment of acne due to their synergistic effect.

Therefore, those of ordinary skill in the art would expect similar increased efficacy in the treatment of acne by combining high doses of orally administered vitamin A with the instant composition, given the teachings of Beerse, et. al. in view of Mezick. The instant composition would have been obvious given the teachings of Beerse, et. al. in view of Mezick.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hasan S. Ahmed whose telephone number is 571-272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'MPW', is positioned above the printed name.

MICHAEL P. WOODWARD  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600